SEP 17 1999

K984358 /S1

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510(k) SUMMARY
OLYMPUS DISTAL ATTACHMENT

A. Submitter's Name, Address, Phone and Fax Numbers

1. Manufacturer of the subject devices

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 22-2 Nishi-Shinjuku, 1-Chome, Shinjuku-ku, Tokyo 163-8610 Japan
Registration No.:	8010047
Address, Phone and Fax Numbers : of R&D Department, Endoscope Division	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 0426-42-5101 FAX 0426-46-2786

B. Name of Contact Person

Name:	Laura Storms-Tyler
Address, Phone and Fax Numbers :	Olympus America Inc. Endoscope Division Two Corporate Center Drive Melville, New York 11747-3157 TEL: (516) 844-5688 FAX: (516) 844-5416

C. Trade Name, Common Name and Classification Name

Trade Name: Olympus Distal Attachment MH-462, -463, -464, -465, -466, -483, -587, -588, -589, -590, -591, -592, -593, -594, -594, -595, -596, -597, -598,
MAJ-289, -290, -291, -292, -293, -294, -295, -296, -297

Common Name : Transparent Cap

Classfication Name: 21CFR 876.1500, Class II, Endoscope and accessories

D. Legally Marketed Device(s) which we claim Substantial Equivalence

Manufacturer	Device Description	510(k)#
Olympus	MH-189	K954451 (Endoscope Accessory for Model CF-140S, CF-Q140L/I and CF-140L/I)

E. Description of the Device(s)

Olympus Distal Attachment has the shape of short transparent tube. Olympus Distal Attachment is to be attached to the distal end of the endoscope to facilitate endoscopic therapy.

F. Intended Use of the Device(s)

Olympus Distal Attachment has been designed to be attached to the distal end of the endoscope to facilitate endoscopic therapy. Olympus Distal Attachment is used for the followings.

1. Gastrointestinal mucosal resection (endoscopic mucosal resection)
2. Keeping the suitable depth of endoscope's view field
3. Helping the endoscope with being inserted into the gastrointestinal tract.

G. Summary of the Technological Characteristics of the Device compared to the Predicate Device(s)

1. Design

In order to maintain the electrical safety, the cap length of the subject devices is longer than the predicate MH-189.

2. Materials

All the patient contacting materials have not been used in Olympus legally marketed Devices.

H. Summary including a Brief Discussion of Determination of Substantial Equivalence

1. Design

The cap length supplies distance enough for the endoscopic therapy using the electrosurgical snares.

2. Materials

The biocompatibility test reports show that new materials does not cause a problem.

I. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, the subject devices do not incorporate any significant change that could affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 1999

Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America Inc.
Two Corporate Center Drive
Melville, NY 11747-3157

Re: K984358
Olympus Distal Attachment (MH and MAJ Models) for Endoscopic Mucosal Resection
Dated: August 31, 1999
Received: September 2, 1999
Regulatory Class: II
21 CFR §876.1500/Procode: 78 KOG

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 984358

Device Name: Olympus Distal Attachment

Indications for Use: The Olympus Distal Attachment is intended to be used for the following:

a) for use with electrosurgical snares for endoscopic mucosal resection within the gastrointestinal tract; and
b) for use in keeping the suitable depth of endoscopic field of view.

Concurrence of CDRH, Office of Device Evaluation ODE

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K984358

(Optional Format 1-2-96)